ARAC
Clinical Trial Network Re-competition

29 September, 2003

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Division of AIDS

National Institute of Allergy and Infectious Diseases,

National Institutes of Health,

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Leadership Meeting
October, 2001

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FACTS

- **The mission of NIAID/DAIDS is to help end the HIV/AIDS epidemic through basic and clinical research.**
- **96% of HIV/AIDS is occurring in developing countries.**
- **An international research agenda will require both scientific and administrative adjustments.**
- **The NIAID/AIDS budget is projected to level off in 2003.**

Thus, we must improve our efficiency and adjust our priorities to accomplish the DAIDS mission.

October 2001

FACTS

- **International research will put unprecedented demands on execution of the research agenda**
  - **Coordination with the *State Department, CDC, DOD*, USAID**
  - **Coordination with local Government Officials (MOH,etc)**
  - **Collaborations with NIAID intramural programs, DMID, OAR, *DIR*, other NIH Institutes (FIC, NICHD, etc.)**
  - **Collaboration with *private Industry*, NGO's ,etc.**
  - ***USA and host country regulatory issues***
  - ***USA and host country pharmacy issues***
  - ***Ethical issues***
  - ***Information Technology support***

FACTS

International research programs must also:

- **establish sustainable host country infrastructures**
- **be conducted as a collaborative partnership with host country scientists**
- **address the needs of the host country**
  - **technology transfer**
  - **training**

The Clinical Trial Networks are the most visible aspect of DAIDS/NIAID and are constantly under scrutiny by the community, the NIH hierarchy, the press and Congress.

THE CHARGE

What steps do we take to improve OUR effectiveness and efficiency in working together to end this epidemic in the face of a stable budget?

When, where, how do the clinical trial networks collaborate, integrate and share?

- research objectives
- sites
- site resources
- laboratories
- databases
- other

DAIDS Clinical Trial Networks

Edmund C. Tramont, M.D.

2 June 2003

Objective

To improve the efficiency and effectiveness of the DAIDS CT Networks..

by taking advantage of (a) the experience of the present CT Network investigators, and (b) the input of those activists groups most interested in the execution of the CT Networks

DAIDS Clinical Trial Networks

are cooperative agreements, and therefore part of or extensions of DAIDS/NIAID/NIH

cooperative agreements are the funding mechanism used when there is substantial involvement of DAIDS during the performance period, but not in day-to-day execution.

What instruments will DAIDS/NIAID use to accomplish its mission?

- **Strategic plans**
- **Strategic partnerships**

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Facts

- **The NIAID/AIDS budget is level.**
- **The Clinical Trial Networks continue to be productive.**
- **>97% of HIV/AIDS is occurring in resource poor developing countries (RPDC).**

DAIDS/NIAID CLINICAL Trial NETWORKS - 2003

AATCG
PATCG
CPCRA
AIEDRP
HPTN
HVTN
ESPIRIT

DoD
CDC
PHIDISA

On 2 June 2003, the Clinical Trial Network leadership met to discuss operational overlap.

On 17 September 2003, the Clinical Trial Network leadership met to discuss scientific priorities and opportunities for cross-fertilization and collaboration.

Why CT Networks?

As opposed to RO1, PO1, etc. CT Networks gain significant efficiencies and effectiveness by:

- *** fostering broad input on key clinical scientific questions**
- *** involving multiple, diverse sites/populations**
- *** providing a forum for investigator exchanges**
- *** developing lab & clinic standards**
- *** sharing databases, SOPs, training modules**

And equally important:

- *** significantly improves DAIDS efficiency in management / oversight**

Reality check: doing research in RPDC

- Lack of adequate Infrastructure
  - adequate clinical facilities
  - adequate laboratory
  - adequately trained personnel
    - physicians, study nurses, paramedical personnel,
    - program/budget managers,
    - biostatistians, data management, IT support.

- From a strategic standpoint, impacting on the epidemic in RPDC will help stabilize economic, social and political disruptions for the world.

The Challenge

Build on the success of the present Clinical Trial Networks in the context of the changing realities of the research demographics that requires an increased International (RPDC) focus.

To best accomplish broad-based collaboration/cooperation requires that

- strategies for improving the efficiency and effectiveness of the DAIDS Clinical Trials Networks requires broad based input from scientific leaders (ARAC), network leaders and the activist community

From DAIDS's standpoint: areas of focus/help where ARAC would be the most help

What questions are best suited to be addressed by:

A domestic CT Network:

- **intensive laboratory investigations,**
- **smaller intensive studies, e.g. phase I/IIa clinical trials,**
- **Collaboration with other IC's on studies requiring sophisticated labs or procedures, e.g. NCI, NIHBD**

An international CT Network:

- **larger clinical trials, e.g. phase IIb/III trials**
- **Collaborations with other IC's, NICHD, NCAMM**

RPDC Challenge

Establishing a multifaceted comprehensive International (RPDC) Network system that is operationally independent but scientifically linked to existing clinical trial networks---

--- will likely require common source funding of international sites and standardized (core) laboratory functions, training and data management rather than the un-coordinated and duplicative situation that now exists.

Investigator Challenge

Ability of “non-Network” investigators to have access and participate in CT Network functions

Help DAIDS formulate the future Clinical Trials Network structure by creating *working groups* to review and advise on CT Network models.

Practical requirement to stimulate cross-Network collaboration

Re-compete CT Networks at the same time to better assure comprehensive integration across the Networks

--- requires extension of AATCG, HVTN,HPTN, CPCRA, ESPIRIT to 2006.

In short

advice in defining the role of the Clinical Trial Networks in the DAIDS/NIAID research portfolio taking into account the changing demographics of the HIV/AIDS epidemic in a time of a level budget.

DAIDS is constantly reminded that

“the buck stops here!”